ARC 5351C

PHARMACY BOARD[657]

Adopted and Filed

Rule making related to accreditation

The Board of Pharmacy hereby amends Chapter 17, "Wholesale Distributor Licenses," and Chapter 43, "Third-Party Logistics Provider Licenses," Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is adopted under the authority provided in Iowa Code sections 155A.17 and 155A.17A.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code sections 155A.17 and 155A.17A.

Purpose and Summary

These amendments allow wholesale distributors and third-party logistics providers (3PL) that are seeking initial or renewal licensure in Iowa to attain accreditation through the National Coalition for Drug Quality and Security (NCDQS), the National Association of Boards of Pharmacy (NABP), or another board-approved accreditation program. These amendments also recognize the updated name of the NABP drug distributor accreditation program.

Public Comment and Changes to Rule Making

Notice of Intended Action for this rule making was published in the Iowa Administrative Bulletin on September 9, 2020, as **ARC 5171C**.

The Board received numerous comments, overwhelmingly suggesting that the Board allow accreditation by NCDQS as a permanent alternative to NABP instead of the originally proposed alternative only for initial licensure. Commenters noted that the standards required to attain NCDQS accreditation are substantially equivalent to those required by NABP. The Board determined that drug supply chain security, and thus public safety, can be reasonably assured with either accreditation.

In response to the comments, the amendments were updated to reflect that either accreditation would meet the minimum standard for initial licensure or renewal. The Board also determined that additional accreditation programs may be initiated and added language to allow future accreditation programs, if approved by the Board, to be equivalent.

Adoption of Rule Making

This rule making was adopted by the Board on November 17, 2020.

Fiscal Impact

This rule making has no fiscal impact to the State of Iowa.

Jobs Impact

After analysis and review of this rule making, no impact on jobs has been found.

Waivers

Any person who believes that the application of the discretionary provisions of this rule making would result in hardship or injustice to that person may petition the Board for a waiver of the discretionary provisions, if any, pursuant to 657—Chapter 34.

Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rule making by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rule making at its regular monthly meeting or at a special meeting. The Committee's meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

Effective Date

This rule making will become effective on February 3, 2021.

The following rule-making actions are adopted:

ITEM 1. Amend paragraph **17.3(1)"c"** as follows:

c. Evidence of current ~~verified accredited wholesale distributors (VAWD)~~ drug distributor accreditation by the National Association of Boards of Pharmacy (NABP), the National Coalition for Drug Quality and Security (NCDQS), or another accreditation body approved by the board. This requirement does not apply to new applicants located in Iowa which must undergo an opening inspection by a board compliance officer or agent of the board prior to issuance of an initial license. Wholesale distributors located in Iowa shall provide evidence of ~~VAWD~~ drug distributor accreditation on or before license renewal.

ITEM 2. Amend subrule 43.3(1) as follows:

43.3(1) *Application.* The applicant shall complete an application which requires demographic information about the 3PL, ownership information, information about the 3PL's registered agent located in Iowa, information about the 3PL's licensure or registration with other state and federal regulatory authorities, criminal and disciplinary history information, and a description of the scope of services to be provided in Iowa. If the applicant is not located in Iowa, the applicant shall submit evidence that the applicant has a valid license or registration in the home state or provide evidence that the home state does not require licensure. The applicant shall provide evidence of current ~~verified accredited wholesale distributors (VAWD)~~ drug distributor accreditation by the National Association of Boards of Pharmacy (NABP), the National Coalition for Drug Quality and Security (NCDQS), or another accreditation body approved by the board. This requirement does not apply to new applicants located in Iowa which must undergo an opening inspection by a board compliance officer or agent of the board prior to issuance of an initial license pursuant to subrule 43.3(3). 3PL distributors located in Iowa shall provide evidence of ~~VAWD~~ drug distributor accreditation on or before license renewal. An application for a 3PL license, including an application for registration pursuant to 657—Chapter 10, if applicable, will become null and void if the applicant fails to complete the licensure process, including opening for business, within six months of receipt by the board of the required application(s).

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EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 12/30/20.